In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-2008V UNPUBLISHED

DEBORAH WOOD.

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 21, 2023

Special Processing Unit (SPU); Entitlement to Compensation; Ruling on the Record; Findings of Fact; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA);

Bruce William Slane, Law Office of Bruce W. Slane, P.C., White Plains, NY, for petitioner.

Neil Bhargava, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

On December 31, 2019, Deborah Wood filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") caused by an influenza ("flu") vaccine administered on September 4, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons described below I find that Petitioner is entitled to compensation.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

Petitioner filed this claim on December 31, 2019. ECF No. 1.

After the claim's initiation in late 2019, an initial status conference was held on April 17, 2020. Respondent noted some potential issues with Petitioner's claim, including a lack of treatment for several years and inconsistencies regarding the site of vaccination. ECF No. 12. Petitioner filed a status report on May 18, 2020, stating that there were no additional vaccination records but that she was awaiting an affidavit from a family friend. ECF No. 13. On May 25, 2020, Petitioner filed an additional affidavit and an amended statement of completion. ECF Nos. 14, 16.

On June 17, 2020, Respondent filed a status report stating that preliminary review of the case revealed some factual and legal issues that required further development, including the site of vaccination and onset. ECF No. 17. Petitioner filed a status report on November 16, 2020, addressing the points raised in Respondent's status report. ECF No. 21. On April 20, 2021 Respondent filed a status report recommending that further proceedings be scheduled to resolve the factual disputes. ECF No. 24.

Following a status conference on March 28, 2022, Petitioner filed a Motion for a Ruling on the Record on May 26, 2022 ("Mot."). ECF No. 29. Petitioner argues therein that she meets the Table Claim requirements for a SIRVA. Mot. at 10-20. Respondent reacted to the Motion on August 11, 2022 ("Opp."). ECF No. 32. Respondent argues that Petitioner has failed to meet the requirements of a Table claim. First, Respondent contends that Petitioner alleges a right SIRVA, but received a vaccination in her left arm. Opp. at 9-12. Second, Respondent argues that onset of Petitioner's injury occurred outside the 48-hour timeframe set forth in the Vaccine Injury Table. *Id.* at 12-14.³ Petitioner filed a reply on August 16, 2022 ("Reply"). ECF No. 33.

II. Petitioner's Medical Records

Prior to vaccination, Petitioner previously reported right shoulder pain in 2015. Ex. 4 at 59, 62. X-rays performed on October 1, 2015, showed degenerative disease of the acromioclavicular joint in the right shoulder and right elbow tendonitis. *Id.* at 91. Petitioner was diagnosed with arthritis of the acromioclavicular joint and prescribed Meloxicam. *Id.* at 59. Her last complaint of shoulder pain prior to 2017 was on October 29, 2015. *Id.* at 59, see also 56-57 (record from November 19, 2015, that does not include complaints of

³ The parties' briefs also addressed Petitioner's success at establishing a causation-in-fact claim, but because I am determining that a Table claim has been demonstrated preponderantly, I do not discuss those arguments.

right shoulder pain). Additionally, Petitioner's medical history includes hyperlipidemia, hypertension, hypothyroidism, and narcolepsy. *Id.* at 48, 58-59.

Petitioner received the flu vaccine on October 4, 2017. Ex. 2 at 2. The administration record states the vaccine was given in Petitioner's left arm. *Id.* A progress note also states that Petitioner was "given Vaccine in Left deltoid.... Petitioner tolerated well." *Id.* at 5.

Several weeks later, on October 30, 2017, Petitioner saw Dr. Dustin Lash at Southern Bone and Joint Specialists for shoulder pain. Ex. 5 at 3-5. The record states that Petitioner had a flu vaccination and has had "pain ever since". *Id.* at 7. Dr. Lash noted that Petitioner was there "for evaluation for right shoulder pain. It started about 3 weeks ago after she had her flu shot in that shoulder." *Id.* at 8. Further, the pain "did not start until a few days after the injection." *Id.* On the medical questionnaire, Petitioner indicated she was suffering from right shoulder pain for three weeks, and the date the problem started was listed as October 9, 2017 (five days after vaccination). *Id.* at 3. X-rays taken that day were unremarkable. *Id.* An examination showed a reduced range of motion, shoulder pain, and tenderness. *Id.* at 8. Petitioner was diagnosed with right subacromial bursitis with pain and received a steroid injection. *Id.* at 8-9.

There is a three-month records gap, and then Petitioner saw a new primary care physician, Dr. Kyle Contini, on February 1, 2018, for a follow-up regarding hypothyroidism. Ex. 6 at 1. Dr. Contini noted shoulder pain, neck, and back pain under review of the systems. An MRI of Petitioner's right shoulder was ordered due to a concern of a rotator cuff tear. *Id.* at 2. The MRI study occurred on February 5, 2018. Ex. 10. It showed chronic degeneration of the AC joint "perhaps with acute bursitis", evidence of impingement and possibly tendinitis, and chronic degeneration and tendinosis of the rotator cuff. *Id.* at 3.

Petitioner again saw Dr. Contini on March 1, 2018. With regard to Petitioner's shoulder pain, Dr. Contini described the MRI findings which showed inflammation but no rotator cuff tear. Ex. 6 at 5. A trial of Voltaren gel was suggested. *Id.* Petitioner next saw Dr. Contini on March 25, 2018. Dr. Contini noted that "[f]or the right shoulder pain we will retry to get Voltaren gel and will refer to Panhandle Orthopedics." *Id.* at 9-10.

On April 9, 2018 Petitioner presented to Dr. Bradley Goeke, an orthopedic surgeon at Bluewater Orthopedics, for right shoulder pain "since October 2017". Ex. 7 at 7. Petitioner stated that "her pain started right after having a flu shot.... She received a cortisone injection from Southern bone and joint in Dothan but it did not help her pain. Since than her insurance has changed and had to switch physicians." *Id.* Dr. Goeke

diagnosed Petitioner with primary osteoarthritis and impingement syndrome of the right shoulder, as well as a sprain of the right rotator cuff capsule. *Id.* at 9. A steroid injection was administered at that time. *Id.* at 10. Petitioner saw Dr. Goeke again on April 12, 2018 for right shoulder pain and limited range of motion. *Id.* at 3. She received another cortisone injection at that time. *Id.* at 5.

On April 26, 2018, Petitioner saw Dr. Contini for a reassessment of her narcolepsy. Ex. 6 at 13-14. Petitioner stated that her right shoulder pain improved "after IA injections with orthopedics." *Id.* Petitioner next saw Dr. Contini on May 24, 2018, for additional concerns about her narcolepsy. *Id.* at 17-20. Shoulder pain was not listed as an ongoing problem and not discussed. Further, Voltaren topical gel was removed from Petitioner's list of current medications. *Id.* at 20. Petitioner saw Dr. Contini again on June 29, 2018. *Id.* at 21-22. There is now no mention of shoulder pain, and her strength and range of motion was noted as normal "for all four extremities." *Id.* at 22.

Petitioner saw Dr. Contini seven additional times between August 6, 2018, and February 5, 2019 for care related to her narcolepsy. Ex. 6 at 25-52. There is no mention of shoulder pain, discomfort, or range of motion issues during these appointments.

III. Affidavit Evidence

Petitioner submitted an affidavit in support of her claim, which was signed on December 26, 2019. Ex. 3. Petitioner states that she received a flu vaccine in her right arm on October 4, 2017. *Id.* at 1. Petitioner further claims that she had no prior right shoulder injuries, and she was "fine up until the October 4, 2017 flu vaccination" despite the evidence of her degenerative right shoulder disease. *Id.* Additionally, she states that her shoulder pain was immense and began immediately after her vaccination. *Id.* at 2. Petitioner explained that she delayed in seeking treatment because she "thought that the pain would subside." Further, she experienced some relief following the subacromial bursa injection, and changed insurance shortly thereafter which necessitated finding a new physician. *Id.* With regard to the reference to her pain beginning on October 9, 2017, Petitioner asserts that she simply made a mistake when describing the onset of her injury. *Id.*

Petitioner also details some of her specific hardships with regard to treatment. For example, she states that physical therapy is difficult to attend because it is "over an hour drive away from where I live." *Id.* at 3. Further, she stated surgery was discussed with Dr. Goeke, but that she was unable to proceed with it due to financial complications.

Jeannette Zimmerman, Petitioner's friend, also submitted an affidavit in support of Petitioner's claim. Ex. 9. Ms. Zimmerman states that "[a] couple days after she received the flu shot, [Petitioner] complained to me about her right arm and shoulder being very painful...and that she had pain in her right arm ever since [the vaccination]." *Id*.

IV. Parties' Arguments

Petitioner requests that I issue a ruling finding that she is entitled to compensation. Mot. at 1. She avers that she meets the Table requirements for a SIRVA. Mot. at 10-18. In particular, Petitioner argues that the vaccination was administered in her right shoulder (Mot. at 10-12; Reply at 1-2), onset of her shoulder pain was within 48 hours of the vaccination, (Mot. at 14-16; Reply at 3-4), and that her injury has persisted for more than six months. Mot. at 18. Petitioner also argues that her right shoulder injuries were caused-in-fact by her October 4, 2017 vaccination. Mot. at 20-23; Reply at 4-5. Respondent argues that Petitioner has failed to show she is entitled to compensation. Specifically, Respondent argues that Petitioner cannot establish a right shoulder SIRVA Table claim because SIRVA in her right arm because the records indicate her vaccination was administered in her left arm (Opp. at 9-12) and that onset of her injury was not within 48 hours of the vaccination (Opp. at 12-14). Respondent also argues that Petitioner has not established her injury was caused-in-fact by the vaccination. Opp. at 14-18.

V. Fact Findings and Ruling on Entitlement

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,⁴ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A

⁴ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42

Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

1. Petitioner Received a Flu Vaccine in her Right Shoulder

Respondent contends that although Petitioner alleges a right SIRVA, the vaccine record indicates the vaccine was given in her left arm. Opp. at 9-12. Respondent's reading of the administration record is correct (see Ex. 2 at 2, 5 (stating the vaccine was administered in Petitioner's left arm)), but his argument does not take into account the totality of the evidence.

The overall medical records, coupled with Petitioner's witness statement, establish that Petitioner consistently and repeatedly reported to treaters right shoulder pain that was caused by a flu vaccine received *in that shoulder*. See, e.g., Ex. 5 at 8 (record stating that Petitioner was being evaluated for right shoulder pain that started "after she had her flu shot in that shoulder"); Further, Petitioner consistently sought care for her right shoulder due to pain she linked to the flu vaccination. Ex. Ex. 7 at 7 (record from Dr. Goeke staring Petitioner's right shoulder pain started "right after having a flu shot").

These records provide sufficient evidence that the vaccine was likely administered in Petitioner's right shoulder to overcome the contrary administration record. The subsequent treatment records gain strength as well given their temporal proximity to the date of vaccination. And the only contrary record comes from the administration record

itself. While that document is both the first contemporaneous item of evidence relevant to this fact dispute, it finds no other corroboration in the overall record – and I do not give it excessive weight simply because it is the "formal" administration record, since it is consistently observed in SIRVA cases in the Program that the administration record is incorrect.

2. No Prior Right Shoulder Condition or Injury Would Not Explain Petitioner's Symptoms

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Petitioner's records show she previously had right shoulder pain two years prior to her vaccination in October 2015. Ex. 4 at 59. At that time, x-rays showed Petitioner had degenerative disease of the acromioclavicular joint and elbow tendonitis. *Id.* at 91. However, after a brief course of treatment consisting of Meloxicam for 30 days, there are no recorded complaints of shoulder pain. *See id.* at 56-57 (record from November 19, 2015, that does not list right shoulder pain as an ongoing issue).

Given that the prior right shoulder condition occurred two years prior to the vaccine, with no subsequent reports of shoulder pain, disfunction, or mobility issues in the intervening timeframe, I find that Petitioner's pre-vaccination degenerative disease and tendonitis would not explain the symptoms experienced after the vaccination. Further, she has demonstrated no other condition that would explain her symptoms. Additionally, Respondent does not contest that Petitioner meets this criterion for a Table SIRVA. Therefore, Petitioner meets this requirement.

3. Onset of Petitioner's Injury Occurred within Forty-Eight Hours of her Vaccination

The medical records, coupled with Petitioner's witness statement, establish onset of her injury close-in-time to vaccination. Admittedly, this presents a closer issue – but sufficient evidence supports Petitioner's contention to find she has met her preponderant evidentiary burden.

Petitioner first sought treatment approximately four weeks after her October 4, 2017 vaccination. In the subsequent timeframe, she consistently reported to treaters that she had experienced symptoms close-in-time to vaccination. Ex. 5 at 7 (October 30, 2017 record stating that she had a flu shot and had "pain ever since"); Ex. 7 at 7 (record from

April 9, 2018 stating that Petitioner's pain "started right after having a flu shot"). These statements, while temporally vague, are not *inconsistent* with a proper Table onset.

Respondent observes, however, that some contemporaneous medical records indicate Petitioner's shoulder pain began *several days* after her vaccination. Opp. at 12-14, citing Ex. 5 at 3, 8 (indicating the onset of Petitioner's injury was October 9, 2017). Respondent's objections have merit, but are outweighed by other evidence. First, the records show that Petitioner reported shoulder pain "after a flu shot" in a relatively timely manner (*i.e.* approximately one month after vaccination). It is common for SIRVA petitioners to delay seeking treatment, thinking the injury will resolve on its own, since patients are often told by medical providers at the time of vaccination to expect some soreness and pain for a period of time after. And individuals also often misconstrue the nature of their injury, and may not inform treaters of all specific facts relevant to its onset until later. Here, the added detail of onset did not "wait" for months before being provided, but began to be reported in a reasonable time post-vaccination.

Second, Petitioner affirmatively and repeatedly linked her shoulder pain to the flu vaccine, beginning as early as October 30, 2017, even if she was not precise about onset. Ex. 5 at 7. And in subsequent medical records she continued to make this association. See, e.g., Ex. 7 at 7 (stating Petitioner's pain "started right after having a flu shot"). Petitioner's affidavit provides additional corroborating evidence for onset of her injury. Petitioner stated that her pain began immediately after her vaccination. Ex. 3 at 2.

Accordingly, and based upon the above, I find there is preponderant evidence that establishes the onset of Petitioner's left shoulder pain was more likely than not within 48-hours of vaccination. The fact that Petitioner did not delay significantly in seeking treatment, and consistently reported pain associated with the vaccination, weigh in her favor, even if some onset references are imprecise – and while the instance of reporting a non-Table onset is contrary, it finds no subsequent corroboration.

4. Petitioner's Pain was Limited to her Right Shoulder

I also find that there is a preponderance of evidence that Petitioner's pain was limited to her right shoulder. Respondent does not contest this aspect of Petitioner's claim, and the records consistently report shoulder pain and loss of range of motion in her right shoulder, which is consistent with other SIRVA cases. Petitioner's medical procedures were also limited to her right shoulder. Accordingly, preponderant evidence establishes that Petitioner's pain was limited to her right shoulder.

5. There is No Evidence of Another Condition or Abnormality

The last criteria for a Table SIRVA state that there must be no other condition or abnormality which would explain a petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). As discussed above, Petitioner's prior history includes reports of right shoulder pain in October 2015. Ex. 4 at 59 (record from October 1, 2015 noting right shoulder pain). But the records also indicate that Petitioner briefly treated with Meloxicam (id.) and did not complain of shoulder pain any time thereafter before her vaccination. Id. at 56-57 (record from November 19, 2015 physical that does not list shoulder pain as an ongoing problem or include any associated treatment).

Petitioner's prior history of degenerative disease and arthritis occurred significantly before the relevant vaccination. Further, because there are no complaints of shoulder pain between November 19, 2015, and October 4, 2017, it is more likely than not that her prior arthritis and degenerative disease would not explain Petitioner's current symptoms. Additionally, Respondent does not contest that Petitioner meets this criterion for a Table SIRVA. Therefore, I find that Petitioner satisfies this requirement.

B. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). The overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received a flu vaccine intramuscularly on October 4, 2017, in the United States. Ex. 2 at 2; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for her injury. Ex. 3 at 3; Section 11(c)(1)(E) (lack of prior civil award).

As stated above, I have found that the onset of Petitioner's right shoulder pain was within 48 hours of vaccination. See 42 C.F.R. § 100.3(c)(10)(ii) (setting forth this requirement). I have also found that there is no other condition which would explain Petitioner's current symptoms. 42 C.F.R. § 100.3(a)(XIV)(B) (listing a time frame of 48 hours for a Table SIRVA following receipt of the influenza vaccine). Therefore, Petitioner has satisfied all requirements for a Table SIRVA.

The last criteria which must be satisfied by Petitioner involves the duration of her SIRVA. For compensation to be awarded, the Vaccine Act requires that a petitioner suffer the residual effects of his or her left shoulder injury for more than six months or required

surgical intervention. See Section 11(c)(1)(D)(i) (statutory six-month requirement). The records demonstrate, and Respondent does not contest, that Petitioner suffered the residual effects of her shoulder injury for more than six months. Ex. 7 at 7 (record from April 9, 2018 indicating Petitioner was still experiencing shoulder pain at that time). Thus, this requirement is also met.

Based upon all of the above, Petitioner has established that she suffered a Table SIRVA. Additionally, she has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

Conclusion

In view of the evidence of record, I find that there is preponderant evidence that Petitioner satisfies the QAI requirements for a Table SIRVA. Further, based on the evidence of record, I find that Petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master